NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

NOVEL LABORATORIES, INC.,

Defendant.

Civil Action No. 11-1341 (PGS)

OPINION

SHERIDAN, U.S.D.J.

This matter comes before the Court upon six motions. Plaintiff Braintree Laboratories, Inc., (Braintree) brings two motions: (1) Motion for Summary Judgment on Defendant's Third, Fourth, and Fifth Counterclaims (ECF No. 141), which seeks summary judgment on Defendant's false marking and unfair competition counterclaims; and (2) Motion for Summary Judgment (Partial) of Infringement (ECF No. 143), which seeks summary judgment on the issues of literal, contributory, and induced infringement. Defendant Novel Laboratories, Inc., (Novel) brings four motions: (1) Motion for Summary Judgment of Non-Infringement (ECF No. 159); (2) Motion for Summary Judgment No. 4 (ECF No. 149), which argues that the patent in suit is invalid for obviousness; (3) Motion to Strike and Preclude Braintree's "A Patient" Infringement Theory and the Adams Declaration (ECF No. 183); and (4) Motion Pursuant to Rule 56(e)(2) (ECF No. 198), which asks for the Court to deem certain facts undisputed. Oral argument was heard on

December 20, 2012. After considering the submissions of the parties, the decision of this Court is set forth for the reasons expressed below.

This memorandum is divided into three sections. Section I lists the material facts, including the background of the SUPREP product at issue in the case, and the background of Novel's proposed generic copy of the SUPREP product. Section II sets forth the legal standard on summary judgment. Section III contains the Court's analysis of the issues raised in the motions.

I

As most middle-aged adults know, there are few things worse than preparing for a colonoscopy. In order for the physician to view the colon clearly, it must be cleansed. The preparation for a colonoscopy includes in-taking large volumes of liquids which cause diarrhea and clear the colon. Since most patients dislike the taste and the large quantity of the solution imbibed, there was significant non-compliance with the preparation protocol. Due to the non-compliance, doctors often found that the colon was not clear enough to successfully perform the colonoscopy.

At the end of the nineties, a Phospho-soda solution was invented which substantially reduced the quantity of solution necessary to prepare the colon. Unfortunately, this product caused electrolyte shifts which resulted in unexpected dangerous side effects, including heart and kidney failure, as well as death in certain cases. In the early 2000's, due to the dangerous side effects, it was apparent that a new preparatory product was needed.

At that time, inventors Cleveland and Fordtran designed a reduced volume colonic purgative formulation called SUPREP Bowel Prep Kit (SUPREP) that avoids the dangerous side

effects and electrolyte imbalances. On September 20, 2005, the inventors were granted U.S. Patent No. 6,946,149 ('149 Patent), which was assigned to Braintree.

Thereafter, Braintree filed a New Drug Application (NDA) with the United States Food and Drug Administration (FDA), and due to the improprieties of the previous purgative, SUPREP was subject to intense scrutiny by the FDA. Through the clinical trials, the FDA sought to review the adequacy of the data to support the safety of the new product because of serious safety concerns with a previous laxative used to prepare patients for colonoscopies – Fleet's Phospho-soda product.

During the clinical testing period, Braintree filed for re-examination of the '149 Patent with the United States Patent and Trademark Office (PTO) in order to clarify its claims. On June 30, 2009, the PTO issued a reexamination certificate amending the claims.

On August 5, 2010, the FDA approved Braintree's NDA No. 22372 for SUPREP. SUPREP is listed by the FDA in the agency's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"). The Orange Book indicates that the '149 Patent has an expiration date of April 30, 2022.

Expeditiously, about three months later (November 8, 2010), Novel filed an Abbreviated New Drug Application (ANDA) No. 202511, for a generic version of Braintree's SUPREP, which, as stated in more detail *infra*, was an exact copy of the SUPREP product. As part of its application, Novel included a paragraph IV certification, which gives notice to the patent holder of a statutorily created act of infringement. 35 U.S.C. § 271(e)(2).

Braintree filed suit against Novel for infringement of the '149 patent pursuant to 35 U.S.C §271(e)(5) on March 9, 2011. Braintree asserts that Novel's Drug Product will infringe

claims 15, 16, 18, 19, 20 and 23. Novel contends that SUPREP does not meet the patent's claims, and as such, copying SUPREP is appropriate because SUPREP has no patent protection.[2]

The SUPREP Product: Composition, Labeling and Administration

SUPREP is a colon cleansing preparation kit containing two 6 ounce bottles. The dose for colon cleansing requires administration of the two bottles of SUPREP in the SUPREP Bowel Prep Kit. SUPREP is indicated for bowel cleansing prior to an adult patient having a colonoscopy procedure. SUPREP is an aqueous, oral solution that contains a flavoring agent. Each six ounce bottle of SUPREP contains 17.5 grams of sodium sulfate, 1.6 grams of magnesium sulfate, and 3.13 grams of potassium sulfate. SUPREP does not include phosphate. Each six ounce bottle of SUPREP is diluted to 16 ounces with water prior to administration. One bottle of SUPREP diluted to sixteen ounces is 473 ml.

The SUPREP label states, in part:

> **2 DOSAGE AND ADMINISTRATION**
>
> SUPREP Bowel Prep Kit should be taken as a split-dose oral regimen.
>
> The dose for colon cleansing requires administration of two bottles of SUPREP Bowel Prep Kit. Each bottle is administered as 16 oz of diluted SUPREP solution with an additional 1 quart of water taken orally. The total volume of liquid required for colon cleansing (using two bottles) is 3 quarts (approximately 2.8 L) taken orally prior to the colonoscopy in the following way:
>
> **Split-Dose (Two-Day) Regimen**
>
> Day prior to colonoscopy:
>
> -A light breakfast may be consumed, or have only clear liquids on the day before colonoscopy. Avoid red and purple liquids, milk, and alcoholic beverages.

[2] Novel's contention means that the inventors of SUPREP incorrectly described the properties of SUPREP in the original patent application, and that they missed the mark again upon reexamination. This contention is analyzed in the infringement section. *See infra* section III.

> -Early in the evening prior to colonoscopy: pour the contents of one bottle of SUPREP Bowel Prep Kit into the mixing container provided. Fill the container with water to the 16 oz fill line, and drink the entire amount.
>
> -Drink two additional containers filled to the 16 oz line with water over the next hour.
>
> Day of colonoscopy:
>
> -Have only clear liquids until after the colonoscopy. Avoid red and purple liquids, milk, and alcoholic beverages.
>
> -The morning of colonoscopy (10 to 12 hours after the evening dose): pour the contents of the second bottle of SUPREP Bowel Prep Kit into the mixing container provided. Fill the container with water to the 16 oz fill line, and drink the entire amount.
>
> -Drink two additional containers filled to the 16 oz line with water over the next hour.
>
> -Complete all SUPREP Bowel Prep Kit and required water at least one hour prior to colonoscopy.

Thus, the SUPREP label instructs patients to ingest one six ounce bottle diluted to 16 ounces with water on the day before colonoscopy, and a second six ounce bottle diluted to 16 ounces with water on the morning before colonoscopy. In Section 12.2, entitled "Pharmacodynamics," the SUPREP full prescribing labeling states, "[t[he osmotic effect of the unabsorbed ions, when ingested with a large volume of water, produces a copious watery diarrhea." In addition to the water used to dilute the SUPREP, the label also instructs patients to consume a total of 64 additional ounces of water during SUPREP administration. After evaluating clinical data submitted by Braintree in connection with NDA No. 22372, the FDA approved SUPREP on August 5, 2010 as a product indicated for cleansing of the colon in preparation for colonoscopy in adults, and approved the language in SUPREP's label.

Novel's Proposed Generic Product is an Exact Copy of SUPREP, and its Label is Copied From SUPREP's Label

Novel's proposed generic version of the SUPREP drug product is named Sodium Sulfate, Potassium Sulfate, and Magnesium Sulfate Oral Solution (the Generic Product). When developing the Generic Product, Novel's objective "was to develop a Sodium Sulfate, (17.5g); Potassium Sulfate, (3.1g); Magnesium Sulfate, (1.6g) Oral Solution, which will meet all the characteristics required to provide the same therapeutic effects as SUPREP." In seeking to avoid the substantial clinical trials to which SUPREP was subjected, Novel's ANDA states that Novel "tried to match [its] product to SUPREP" to develop a "stable and palatable formulation meeting all the characteristics to provide the same therapeutic effect as SUPREP." Novel's ANDA states that the Generic Product contains the "active ingredients sodium sulfate, potassium sulfate and magnesium sulfate in the same concentration and dosage form" as SUPREP. Novel's ANDA also states that the Generic Product is a "stable and palatable formulation meeting all the characteristics to provide the same therapeutic effect as SUPREP."

The Generic Product is **"**exactly the same as [SUPREP] and contains the same inactive ingredients." Novel's ANDA states that "[t]here is no difference between [SUPREP] and Novel's drug product formulation." Novel's Generic Product contains the same active ingredients (sodium sulfate, potassium sulfate and magnesium sulfate) in the same concentration as that of Braintree's SUPREP. The Generic Product is chemically the same as SUPREP. The Generic Product is pharmaceutically and therapeutically equivalent to Braintree's SUPREP. The only difference between SUPREP and the Generic Product is the choice of flavoring. Novel's proposed label for the Generic Product is copied from the FDA approved product label and package insert for Braintree's SUPREP.

II

Summary judgment is appropriate under Fed. R. Civ. P. 56(c) when the moving party demonstrates that there is no genuine issue of material fact and the evidence establishes the moving party's entitlement to judgment as a matter of law. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). A factual dispute is genuine if a reasonable jury could return a verdict for the non-movant, and it is material if, under the substantive law, it would affect the outcome of the suit. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). "In considering a motion for summary judgment, a district court may not make credibility determinations or engage in any weighing of the evidence; instead, the non-moving party's evidence 'is to be believed and all justifiable inferences are to be drawn in his favor.'" *Marino v. Indus. Crating Co.*, 358 F.3d 241, 247 (3d Cir. 2004) (*quoting Anderson*, 477 U.S. at 255).

Once the moving party has satisfied its initial burden, the party opposing the motion must establish that a genuine issue as to a material fact exists. *Jersey Cent. Power & Light Co. v. Lacey Twp.*, 772 F.2d 1103, 1109 (3d Cir. 1985). The party opposing the motion for summary judgment cannot rest on mere allegations and instead must present actual evidence that creates a genuine issue as to a material fact for trial. *Anderson*, 477 U.S. at 248; *Siegel Transfer, Inc. v. Carrier Express, Inc.*, 54 F.3d 1125, 1130-31 (3d Cir. 1995). "[U]nsupported allegations . . . and pleadings are insufficient to repel summary judgment." *Schoch v. First Fidelity Bancorp.*, 912 F.2d 654, 657 (3d Cir. 1990); *see also* Fed. R. Civ. P. 56(e) (requiring nonmoving party to "set forth specific facts showing that there is a genuine issue for trial"). Moreover, only disputes over facts that might affect the outcome of the lawsuit under governing law will preclude the entry of summary judgement. *Anderson*, 477 U.S. at 247-48. Summary judgment is appropriate "[w]here the record taken as a whole could not lead a rational trier of fact to find for the non-

moving party." *Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (internal citation and quotations omitted).

III

Braintree contends that the Generic Product infringes claims 15 and 18 of the '149 patent, and will induce and contribute to infringement of claims 19, 20 and 23 of the '149 patent. Novel contends that the undisputed facts establish its entitlement to summary judgment of non-infringement. The Court will evaluate these cross motions together. First, the disputed claims are presented and then the acts of infringement are discussed.

The Disputed Claims

As amended after reexamination, claim 15 is an independent claim covering a composition, reciting:

> 15. A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution comprising an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

Claim 16 is a dependent claim covering a composition, reciting:

> 16. A composition according to claim 15, wherein the solution comprises between about 2 grams and about 40 grams of Na_2SO_4, between about 2 grams and about 20 grams of $MgSO_4$, and between about 1 gram and about 10 grams of K_2SO_4.

As amended after reexamination, claim 18 is an independent claim covering a composition, reciting:

> 18. A composition for inducing purgation of the colon of a patient, the composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution consisting essentially of an effective amount of Na_2SO_4, an effective amount of $MgSO_4$, and an effective amount of K_2SO_4, wherein the composition does not produce any clinically significant electrolyte shifts and does not include phosphate.

Claim 19 is a dependent claim covering a method, reciting:

> 19. A method for inducing colonic purgation in a patient, comprising the steps of: (a) orally administering an effective amount of the composition of claim 18 to a patient; and (b) allowing the administered composition to induce colonic purgation.

Claim 20 is a dependent claim covering a method, reciting:

> 20. A method for inducing colonic purgation in a patient, comprising the steps of: (a) orally administering an effective amount of the composition of claim 15 to a patient; and (b) allowing the administered composition to induce colonic purgation.

Claim 23 is a dependent claim covering a method, reciting:

> 23. A method for inducing colonic purgation in a patient according to claim 20, wherein the effective amount of the composition is administered in two or more doses within a treatment period.

Literal Infringement of Claims 15 and 18 of the '149 Patent

There is a two-step analysis for determining patent infringement under 35 U.S.C. § 271: "first, the court determines the meaning of the disputed claim terms, then the accused device is compared to the claims as construed to determine infringement." *Acumed LLC v. Stryker Corp.*, 483 F.3d 800, 804 (Fed. Cir. 2007) (citation omitted). For literal infringement, the accused product or process must "contain each limitation of the claim exactly" and there cannot be "any deviation from the claim." *Litton Sys. v. Honeywell*, 140 F.3d 1449, 1454 (Fed. Cir. 1998); *see also Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1330 (Fed. Cir. 2001).

For the reasons stated below, the Court finds that the Generic Product literally infringes claims 15 and 18 of the '149 Patent, because each limitation of claims 15 and 18 is met. According to Novel's admissions and the undisputed facts, there is no legitimate dispute that Novel's copy of SUPREP meets each claim limitation.

The Court begins its infringement analysis with the important fact that the Generic Product is exactly the same as SUPREP. Accordingly, if SUPREP is covered by the '149 patent

– if each claim limitation is met by SUPREP – then the Generic Product infringes. Below, the Court analyzes whether the Generic Product meets each of the claim limitations.

The Generic Product Does Not Produce Clinically Significant Electrolyte Shifts

The parties dispute whether the Generic Product meets the "clinically significant electrolyte shifts" element of claims 15 and 18 of the '149 Patent. Claims 15 and 18 of the '149 patent both include the phrase "wherein the composition does not produce any clinically significant electrolyte shifts." This phrase was one of the terms subject to a *Markman* ruling. At the *Markman* phase, the Court rejected both of the parties' proposed definitions, and determined its own construction. The Court determined that the disputed term "clinically significant electrolyte shifts" meant "alterations in blood chemistry that are outside the normal upper or lower limits of their range or other untoward effects."

As noted above, the Court's definition is different than those proposed by the parties and argued for at the *Markman* hearing. After a thorough review of the intrinsic evidence, the Court found that the parties' definitions were overly complicated, subject to broad physician review, and not within the intended meaning of the inventors. After the Court crafted its own definition, a telephone conference was held with the parties to review the definition. At that time, only Braintree raised an issue with the Court's construction of the "clinically significant electrolyte shifts" term, and the Court responded by deleting the allegedly problematic clause[3] from the final opinion. Neither party challenged or requested any further clarification of the Court's definition. Yet, the definition has turned into a major point of contention in the summary judgment motions

[3] The Court deleted the clause, "But no one has suggested same," from the beginning of the following sentence: "But no one has suggested same, hence the definition in the specification is more preceise than the construction of the parties, and is adopted."

presently before the Court. Like the parties' proposed constructions, the Court's first construction of the term was, apparently, imprecise, and therefore must be clarified.

Novel claims that that clinical data produced by Braintree shows that SUPREP causes shifts in electrolyte levels outside the normal range in some patients. In Novel's reading of the Court's claim construction, the production of such shifts would take SUPREP outside of claims 15 and 18. Braintree's position on the Court's claim construction is that it implies that something more than just shifts outside the normal range are needed to satisfy the claim term, and as such SUPREP falls within claims 15 and 18. Novel seems to ignore the phrase "or other untoward effects", likely because the phrase is meant to show that electrolyte abnormalities are not clinically significant electrolyte shifts unless they lead to serious adverse health effects, like those caused by Phospho-soda. (*See e.g.*, Supp. Lumelsky Decl., Ex. 33, Peura 2/27/12 Tr., 140:24-142:8 (explaining how "or other" relates "untoward effects" back to alterations in blood chemistry)). Indeed, the Court's claim construction opinion recognized that "other untoward effects" refers to the serious side effects of Phospho-soda. (*See* ECF. No. 130, at 10 ("It appears that 'untoward effects' may refer to those fatal side effects of the phospho soda solution because such side effects are referred to in the specification")). However, since the Court's definition was apparently imprecise, the Court stresses here that in its view, the term "clinically significant electrolyte shifts" necessarily connotes something more than just electrolyte shifts outside normal ranges.

The ability to induce purgation without causing clinically significant shifts is a fundamental aspect of the invention. (*See, e.g.,* '149 Patent, at Col. 1:6-12 ("This formulation is effective to produce colonic purging to prepare the colon for surgical or diagnostic procedures and surprisingly does not cause clinically significant changes in electrolyte balance"); *Id.* at

Abstract ("Unlike prior art, this composition is useful for the cleansing of the bowel . . . without producing clinically significant changes in bodily function")). The formulations were designed to replace other colon preparations that caused "massive electrolyte and fluid shifts that are clinically significant to the patient," leading to serious health problems, even death. (*Id.* at Col. 2:40-44 (*citing* U.S. Food and Drug Administration, Center for Drug Evaluation and Research, Sep. 17, 2001 (Lumelsky Decl. Ex. 8); 2002 Physician's Desk Reference, prescribing information for Fleet's Phospho Soda and InKine Pharmaceutical's Visicol® (Lumelsky Decl. Ex. 7)); *see also Id.* at Col. 3:10-14 ("clinically significant electrolyte and fluid shifts . . . have been known to cause deaths."); *Id.* at Col. 2:56-61 ("All of these products have been seen to cause clinically significant electrolyte disturbances and fluid shifts, and disturbances in cardiac and renal function when administered to patients")). To accomplish this goal, the inventors described and claimed formulations that do not cause electrolyte shifts leading to serious health problems for the patient. Therefore, as stated above and suggested in the Court's claim construction, the clinically significant electrolyte shifts mentioned in the patent are alterations in blood chemistry that are both outside the normal upper or lower limits of their range and accompanied by or manifested as other untoward effects, such as disturbances in cardiac and renal function as disclosed in the patent specification.

SUPREP was never associated with a serious adverse event like those described in the FDA-approved label or in the '149 patent – events such as cardiac abnormalities, renal failure, and death. (*See* '149 patent, at Col. 2:56-62 ("All of these [prior art] products have been seen to cause clinically significant electrolyte disturbances and fluid shifts, and disturbances in cardiac and renal function when administered to patients"); *id.* at Col. 4:23-27; *see also* Peura Decl. at ¶ 72). Because SUPREP has never been associated with any serious adverse events related to

electrolyte abnormalities, it has not produced (and does not produce) clinically significant electrolyte shifts in patients. Given that Novel's proposed version of SUPREP is a copy of Braintree's product, it also will not produce clinically significant electrolyte shifts upon administration to a patient. As such, Novel's claim that SUPREP does not meet the limitations of claims 15 and 18 solely because the electrolyte shifts were above or below normal limits lacks merit.

But the Court's decision rests not only on the above clarification of the claim construction, but also on the definition of "a patient" in the preamble of claims 15 and 18, and the Court's opinion that it applies to the clause "wherein the composition does not produce any clinically significant electrolyte shifts in a patient" of the claims.[4] Consistent with Federal Circuit precedent, the Court agrees with Braintree's contention that the term "a" as it appears in the preamble of claims 15 and 18 means one or more. *See KCJ Corp.*, 223 F.3d at 1356; *see also Baldwin Graphic Sys.*, 512 F.3d at 1342 (Fed. Cir. 2008). The '149 patent does not appear to provide a special definition of the term "a" to suggest a different meaning. While Novel asserts that *KCJ Corp.* and *Baldwin Graphic Sys.* do not support defining "a" as "one or more" in claims 15 and 18 because, unlike in those cases, "a" in claims 15 and 18 does not follow the term "comprising", the Court does not read those cases in such a limited fashion.

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Commc'ns Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir. 1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is necessary to give life, meaning, and vitality to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v.*

[4] Novel moves to bar this argument on the ground it violates the Local Patent Rules. *See*, discussion infra at p. 29.

Hewlett-Packard Co., 182 F.3d 1298, 1305 (Fed. Cir. 1999) (internal citations and quotations omitted). The question of whether a preamble is limiting "involves examination of the entire patent record to determine what invention the patentee intended to define and protect." *Rowe v. Dror*, 112 F.3d 473, 478 (Fed. Cir. 1997).

The preambles of claims 15 and 18 read: "[a] composition for inducing purgation of the colon of a patient." Given that the Court has held the definition of "a" is "one or more", the term "a patient" means one or more patients. As such, based on its review of the entire patent record before it, the Court finds that "a patient" is a limitation of the claims, as it appears that the administration of the composition and evaluation of the electrolyte levels in claims 15 and 18 were meant to be done on a per patient basis. Accordingly, the Court finds that the "a patient" limitation applies to the "wherein the composition does not produce any clinically significant electrolyte shifts in a patient" element of the claims.

There is no dispute that at least one patient to whom SUPREP is administered will experience, or has experienced, no clinically significant electrolyte shifts. There is also no dispute that the Generic Product is exactly the same as SUPREP and contains the same inactive ingredients. Accordingly, for this additional reason, the Court holds that Braintree has demonstrated that its product, and the Generic Product, meets the "clinically significant electrolyte shifts" element of claims 15 and 18 of the '149 patent.[5]

The Generic Product Induces Purgation of the Colon of a Patient

Claims 15 and 18 require a composition that will induce purgation of the colon when it is administered to a patient. ('149 Patent, at claims 15 and 18). The Court construed the claim

[5] Novel has not had the opportunity to review the Court's clarification of its claim construction contained in this opinion. Therefore, as the Court stated at oral argument on December 20, 2012, Novel may raise any arguments that stem from the Court's analysis *supra* in a motion for reconsideration.

term "purgation" to mean "an evacuation of a copious amount of stool from the bowels after oral administration of the solution." Novel essentially makes two arguments regarding the "purgation" claim limitation: (1) Novel argues that while two bottles may cause a purgation, one bottle of SUPREP – meets the volume limitations of the claims at issue – does not cause a purgation; and (2) Novel argues that, while administration of two bottles for colon cleansing is the indicated use for SUPREP, administration of one bottle of SUPREP to cause purgation is an "off-label use", and therefore can never infringe the disputed claims.

The Court holds that the Generic Product meets the "purgation" claim limitation. One bottle of the SUPREP product, used as directed, is sufficient to induce a "purgation," as the Court has construed the term. (*See* Supp. Peura Decl. ¶ 125). While Novel argues that one bottle of SUPREP does not cause a purgation, it offers no evidence whatsoever, save for unsworn argument, to refute Braintree's evidence and to support its contention. While some of the evidence cited by Braintree does not support the contention that one bottle of SUPREP causes a purgation,[6] the affidavit of Braintree's expert, Dr. Peura, clearly states that one bottle of the SUPREP product, used as directed, is sufficient to induce a purgation. Braintree has shown that no genuine issue of material fact exists as to whether SUPREP causes colonic purgation, so it is Novel's burden to offer admissible evidence that a genuine fact issue compels a trial, not just "some metaphysical doubt as to the material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986). By failing to submit any affirmative evidence that shows SUPREP or the Generic Product does not induce colonic purgation, Novel has failed to meet its burden as to this claim limitation.

[6] Braintree cites to Novel's proposed label and the testimony of Scott Talbot, James Garegnani, Dr. Johanson, and Dr. Goldfarb to support its contention that one bottle of SUPREP (or one bottle of Novel's copy of SUPREP) will induce colonic purgation in a patient. However, very little of the cited evidence is specific to the effects of *one bottle* of SUPREP.

In addition, Novel's argument that administration of one bottle of SUPREP to cause purgation is an "off-label use", and therefore can never infringe the disputed claims, is without merit. As this Court recognized in its Claim Construction Order, purgation is the method to achieve the goal of colon cleansing. (*See* ECF. No. 130 at 6; *see also* Supp. Peura Decl. ¶ 125). Because purgation is the method by which SUPREP achieves the FDA-approved indication of colon cleansing, purgation cannot be an off-label use for SUPREP. As Braintree points out, Novel's argument is akin to an assertion that using an asthma medication that improves breathing is off-label if it works by reducing airway inflammation; reduction of airway inflammation is the method by which the medication achieves the goal of improved breathing. The cases Novel cites in support of its assertion do not involve methods to achieve an FDA-approved indication, and are therefore inapplicable. The cases also relate to method of use claims only – in each case, the claims at issue covered specific uses of a drug to treat disease, not the drug composition itself. *See Bayer Schering Pharma AG v. Lupin, Ltd.*, 676 F.3d 1316, 1319 (Fed. Cir. 2012); *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1048, 1057 (Fed. Cir. 2010); *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1352 (Fed. Cir. 2003); *Allergan v. Alcon Labs.*, 324 F.3d 1322, 1323 (Fed. Cir. 2003). These cases provide no guidance to the Court with respect to drug composition claims, such as claims 15 and 18, as nothing in the cited cases addresses the fact that here, Novel intends to make, offer to sell, and sell a product that directly infringes the '149 patent.

The Generic Product is a Composition Comprising from About 100 ml to About 500 ml of an Aqueous Hypertonic Solution

Claims 15 and 18 require a composition comprising from about 100 ml to about 500 ml of an aqueous hypertonic solution. For the following reasons, the Generic Product meets this claim limitation. Novel's copy of SUPREP is an aqueous hypertonic solution. (Response to

Request For Admission No. 25; Johanson 9/6/12 Tr. at 252:22-253:5; Goldfarb 9/14/12 Tr. At 242:13-25; Peura Decl. at ¶¶ 64-65). Novel's copy of SUPREP requires that a patient ingest "two bottles of an oral solution," each of which will be 6 ounces diluted to 16 ounces when consumed. (*See e.g.*, Response to Request For Admission No. 28). Sixteen ounces is equivalent to 473 ml, which is within the claimed range of claims 15 and 18 of the '149 patent. (*See* Response to Request for Admission Nos. 33 and 34).

Novel argues that Braintree has admitted to the PTO and in publications co-authored by one of the '149 patent inventors that the volume of SUPREP solution needed for inducing purgation of the colon is 946 milliliters, i.e., two bottles of SUPREP each diluted to 16 ounces. However, these alleged admissions do nothing to contradict the fact that, as explained above, one bottle of SUPREP is sufficient to cause purgation of the colon. Given that one bottle is sufficient to induce purgation, there is no genuine dispute that the Generic Product constitutes a composition of from about 100 ml to about 500 ml of an aqueous hypertonic solution, as required by the claims.

The Generic Product Comprises an Effective Amount of Na_2SO_4, an Effective Amount of $MgSO_4$, and an Effective Amount of K_2SO_4

Claims 15 and 18 require an "effective amount" of three sulfate salts. "Effective amount" has been construed to mean "the amount and combination of salt necessary to produce a colonic purgation, while not producing clinically significant electrolyte shifts." (ECF. No. 130 at 9). Therefore, no specific amount of each sulfate salt is required; all that is required is that the three salts be used in combination in such a way that produces purgation but does not cause clinically significant electrolyte shifts. As it is undisputed that SUPREP and the Generic Product contain the three sulfate salts, it is also beyond dispute that SUPREP and the Generic Product

meet this claim limitation if it can be shown – as it has – that the "induces purgation" and "clinically significant electrolyte shifts" limitations are also met.

Accordingly, for the reasons set forth above, the Court holds that the Generic Product literally infringes claims 15 and 18 of the '149 patent.

Induced and Contributory Infringement

The Court now analyzes Braintree's additional claims of induced and contributory infringement.

Induced Infringement of Claims 19, 20 and 23 of the '149 Patent

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). A claim of induced patent infringement arises where "the alleged infringer knowingly induced infringement and possessed specific intent to encourage another's infringement." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 2010 WL 4286284, at *12 (Fed. Cir. 2010) (*quoting DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006)); *see also C.R. Bard, Inc. v. Advanced Cardiovascular Syss., Inc.*, 911 F.2d 670, 675 (Fed. Cir.1990) ("A person induces infringement under § 271(b) by actively and knowingly aiding and abetting another's direct infringement") (citation omitted).

"Intent can be shown by circumstantial evidence, but the mere knowledge of possible infringement will not suffice." *Vita-Mix Corp. v. Basic Holding, Inc.*, 581 F.3d 1317, 1328 (Fed. Cir. 2009) (citation omitted). As such, a plaintiff alleging induced infringement must satisfy the "rigorous" standard of demonstrating that the defendant had a specific intent to encourage infringement. *Best Med. Intern., Inc. v. Accuray, Inc.*, 2010 U.S. Dist. LEXIS 128367, 2010 WL 5053919, at *6 (W.D. Pa. Dec. 2, 2010) (citing *Broadcom Corp. v. Qualcomm Inc.*, 543 F.3d 683, 697-98 (Fed. Cir. 2008)).

Claims 19 and 20 of the '149 patent claim *methods* for using the compositions of claims 15 and 18. Specifically, claim 19 claims a method for inducing colonic purgation in a patient, comprising two steps: (1) orally administering an effective amount of the composition of claim 18 to a patient; and (2) allowing the administered composition to induce colonic purgation. Claim 20 claims a method for inducing colonic purgation in a patient, comprising two steps: (1) orally administering an effective amount of the composition of claim 15 to a patient; and (2) allowing the administered composition to induce colonic purgation. Braintree argues that there is no legitimate dispute that Novel intends to, and will induce, patients and doctors using the Generic Product to infringe claims 19 and 20.

As set forth above, the Generic Product includes an effective amount of the composition of claims 15 and 18, has the same active ingredients in the same amounts as SUPREP, and will induce colonic purgation if taken as directed. In addition, physicians and patients are instructed to administer the Generic Product in a manner that induces colonic purgation. Finally, Novel has admitted that it intends for doctors and patients to use the Generic Product according to its proposed product label and package insert, and its generic copy will be sold with a proposed product label and package insert that are copied from Braintree's FDA-approved label.

Novel's proposed label instructs patients to drink two bottles of solution both the evening before colonoscopy and the day of colonoscopy. That is, the Generic Product – which infringes claims 15 and 18 – will be orally administered twice (in two bottles) during a treatment period. Therefore, through its proposed label, Novel intentionally induces patients to ingest a composition infringing claims 15 and 18.

In addition, as stated above, if a patient ingests the Generic Product according to its proposed label, the product will cause colonic purgation, and the label clearly informs patients

and doctors that the Generic Product cleans the colon by causing diarrhea. Thus, the purpose of Novel's proposed labeling is to instruct patients to take the solution orally and to allow the composition to induce purgation of the colon.

Therefore, it is beyond dispute that Novel, through its proposed label, induces infringement of claims 19 and 20 of the '149 patent by instructing patients and doctors to: (1) orally administer an effective amount of the composition of claims 15 and 18 to a patient; and (2) allow the administered composition to induce colonic purgation.

Claim 23 of the '149 patent is a method for inducing colonic purgation in a patient according to claim 20, where the composition is administered in two or more doses within a treatment period. If approved by the FDA, Novel's proposed label will instruct and induce patients to practice each and every element of claim 23. As stated above, each bottle of the Generic Product, if administered according to the proposed label, meets the limitations of Claim 20. With respect to the additional claim element "the effective amount of the composition is administered in two or more doses within a treatment period," patients taking the Generic Product as directed by Novel's label will directly infringe claim 23, and Novel's proposed labeling induces such infringement. Novel's label instructs patients to practice claim 20 twice in the treatment period – in the evening and again the next morning. Furthermore, Novel intends for patients to follow the regimen described in its proposed label. As stated above, consumption of each bottle of Novel's copy of SUPREP induces purgation, thereby satisfying the limitations of claim 23.

As stated above, any patient who uses the Generic Product in accordance with the explicit instructions in Novel's proposed label will directly infringe each and every element of claims 19, 20, and 23 of the '149 patent. "[T]he requisite intent to induce infringement may be inferred

from all of the circumstances." *Broadcom*, 543 F.3d at 699. "In the context of specific intent, it is irrelevant that some users may ignore the warnings in the proposed label. The pertinent question is whether the proposed label instructs users to perform the patented method." *AstraZeneca*, 633 F.3d at 1060. Therefore, Novel's specific intent to induce infringement can be inferred from the proposed label as a matter of law, as the proposed label explicitly instructs patients to use the Generic Product in a manner that will directly infringe the claims. Novel intended to cause the acts that constitute direct infringement, and Novel knew or should have known that its action would cause the direct infringement. *See id.* at 699.

Novel was aware of the '149 patent when it filed ANDA 202411 with its proposed labeling. Novel is seeking FDA approval to market the Generic Product with proposed labeling that would instruct others to directly infringe claims 19, 20, and 23 of the '149 patent. It is easily inferred that Novel knew or should have known that its actions would cause patients to directly infringe the claims. Upon gaining FDA approval, Novel will provide instructions directing patients to perform the actions that will directly infringe the claims 19, 20 and 23 of the '149 patent. Moreover, there is no way for patients to use the Generic Product in a way that does not infringe at least claims 19 and 20. Thus Novel's intent to induce infringement of the '149 patent is apparent.

Contributory Infringement of Claims 19, 20, and 23 of the '149 Patent

Section 271(c) prohibits the sale of a product that can be used in a patented method if the product is "not a staple article or commodity of commerce suitable for substantial noninfringing use." A defendant is thus liable for contributory infringement if: (1) it sells or offers for sale a material component of a composition for use in a patented method; and (2) the component is not a staple article or commodity of commerce suitable for substantial non-infringing use. *See* 35

U.S.C. 271(c). The Generic Product will contribute to the infringement of claims 19, 20, and 23 of the '149 patent because the Generic Product has no substantial noninfringing uses, and is known by Novel to be especially made to practice the asserted method claims of the patent in suit. *See i4i Ltd. P'ship v. Microsoft Corp.*, 598 F.3d 831, 850-851 (Fed. Cir. 2010). There is no dispute that Novel is aware of the infringing use of the Generic Product. The Generic Product also constitutes a material part of claims 19, 20 and 23 of the '149 patent, as the Generic Product is the sole physical object necessary to practice these claims. In seeking approval to market the Generic Product, Novel demonstrated knowledge that the Generic Product is especially made or adapted for use in infringement of the '149 patent, and it is not a "staple article of commerce suitable for substantial noninfringing use." *Ricoh Co., Ltd. v. Quanta Computer Inc.*, 550 F.3d 1325, 1337 (Fed. Cir. 2008).

A generic product designed to treat the same disorders as the branded product and matching the branded product's indications has no substantial noninfringing use. *See Wyeth v. Sandoz, Inc.*, 703 F. Supp. 2d 508, 522-23 (E.D.N.C. 2010). Here, the Generic Product can be used only to infringe because the only FDA-authorized use for SUPREP, and thus for Novel's identical proposed copy of SUPREP, is the patented use: "an osmotic laxative indicated for cleansing of the colon in preparation for colonoscopy in adults." Novel is barred by federal law from selling a federally regulated drug for any other use. *See 21 C.F.R.* § 202.1(e)(4). Therefore, the Generic Product would have an identical indication as SUPREP, and thus, would have no substantial noninfringing use. Accordingly, the Generic Product will contribute to the infringement of claims 19, 20, and 23 of the '149 patent.

Motion for Summary Judgment on Invalidity

Also before the Court is the Motion for Summary Judgment No.4: Invalidity Based on Obviousness. (ECF No. 149). Defendants seek to have the asserted claims declared invalid. Defendants assert that summary judgment is warranted on the grounds of obviousness, stating that "[t]he '149 patent claims nothing more than known cathartic agents. A person of ordinary skill, based on available knowledge taught by the prior art, could have determined with reasonable predictability and routine experimentation how to combine those known purgatives into a drug covered by the asserted claims."

To prevail on a defense of invalidity for obviousness, Defendants must demonstrate by clear and convincing evidence that the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. 35 U.S.C. § 103(a). "A party seeking to invalidate a patent based on obviousness must demonstrate 'by clear and convincing evidence that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.'" *Id.* (*citing Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1361 (Fed. Cir. 2007)).

The Supreme Court has enumerated four factors to be considered by courts to assess whether an invention is obvious. *Takeda v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (*citing Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966)). The four factors are: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary

considerations, or "objective indicia of non-obviousness." *Id.*; *see also KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 405 (2007).

In *KSR International Co. v. Teleflex Inc.*, the Supreme Court cautioned against (1) a rigid application of the teaching, suggestion and motivation (TSM) test, and (2) a rigid application of using an "obvious to try" analysis when there is pressure to solve a problem with "a finite number of identified, predictable solutions." 550 U.S. 398, 127 S. Ct. 1727, 1741-42 (2007). Instead, the Court advocated a "common sense" approach to determining obviousness. *See id.* at 1741-43. Specifically, the Court explained that "any need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining elements in the manner claimed." *Id.* at 1742. The Court reasoned that, "if a technique has been used to improve one device, and a person of ordinary skill in the art would recognize that it would improve similar devices in the same way, using the technique is obvious unless its actual application is beyond his or her skill." *Id.* at 1740. However, even in light of the new approach advocated by *KSR*, this Court must be cautious to avoid the use of hindsight when considering Defendant's obviousness argument. Thus,

> [i]n conducting an obviousness analysis, [a] factfinder should be aware . . . of the distortion caused by hindsight bias and must be cautious of arguments reliant upon ex post reasoning. This is because the genius of invention is often a combination of known elements that in hindsight seems preordained.

In re Omeprazole Patent Litig., 490 F. Supp. 2d 381, 2007 U.S. Dist. LEXIS 39670, at *400-01 (S.D.N.Y. May 31, 2007) (citation omitted) (quoting KSR, 550 U.S. at 420); see also *Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1138 (Fed. Cir. 1985).

This Court finds that genuine issues of material fact exist in this case, including but not necessarily limited to: the scope, content and teaching of the prior art; differences between the prior art and the '149 Patent; whether the prior art demonstrated that the use of sulfate salts as

hypertonic solutions was predictable; and secondary considerations such as whether there was a long felt need for, or failure of others or unexpected results in the development of the claimed invention. Accordingly, these factual disputes preclude a finding at the summary judgment stage. These disputes present complicated questions of fact best resolved at trial. Defendant's motion is therefore denied.

Motion for Summary Judgment on Defendant's Counterclaims

Braintree moves for summary judgment on Novel's third, fourth, and fifth counterclaims. (ECF No. 141). Novel's third counterclaim alleges, *inter alia*, "[b]y listing the '149 patent in the Orange Book and marking its product inserts with the '149 patent, Braintree falsely marked its prescription SUPREP product under 35 U.S.C. § 292. Braintree listed the '149 patent in the Orange Book as covering SUPREP and marked the '149 patent on its product inserts for SUPREP with an intent to deceive the public." (ECF No. 63, ¶ 134). Novel's fourth counterclaim alleges unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), in that, *inter alia*, "Braintree's actions in falsely marking SUPREP with the '149 patent, and listing the '149 patent in the Orange Book in connection with SUPREP, constitute unfair competition and false advertising in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)." (ECF No. 63, ¶ 193). Novel's fifth counterclaim alleges, *inter alia*, "Braintree has made representations to the public, or caused such representations to be made, that SUPREP is covered by one or more claims of the '149 patent," and Braintree's "acts and conduct . . . constitute unfair competition and unfair business practices contrary to the laws of the State of New Jersey." (ECF No. 63, ¶¶ 200, 204). Braintree moves for summary judgment of Novel's third, fourth, and fifth counterclaims. (ECF No. 141).

Initially, the Court notes that Novel's third, fourth, and fifth counterclaims all stem from Braintree's alleged false or improper listing of the '149 patent in the Orange Book as covering SUPREP, and alleged false or improper marking of SUPREP with the '149 patent. The Hatch-Waxman Act provides an aggressive trial procedure for patent infringement and invalidity claims. Here, the false marking and unfair competition counterclaims raised by Novel, especially with respect to damages issues, are far beyond the Hatch-Waxman Act's criteria for quick patent dispute adjudication.

Further, Novel's counterclaims do not appear to comport with the limited counterclaims available under the Hatch-Waxman Act for improper listing of a patent in the Orange Book. *See* 21 U.S.C. § 355(j)(5)(C)(ii)(I). Other district courts in this district have reached a similar conclusion in Hatch-Waxman Act cases where the defendant brought a counterclaim for patent misuse in which the underlying facts alleging the improper listing of a patent in the Orange Book were substantially similar to Novel's false marking and unfair competition counterclaims. *See Takeda Pharmaceutical Co., Limited v. Zydus Pharmaceuticals USA, Inc.*, 2011 WL 2115819 (D.N.J., May 25, 2011); *Schwarz Pharma, Inc. v. Teva Pharmaceuticals USA, Inc.*, 2005 WL 4158850 (D.N.J., February 4, 2005).

Notwithstanding the above, even if the Hatch-Waxman Act does not preclude Novel's third counterclaim alleging false marking under 35 U.S.C. § 292, Novel cannot satisfy the requisite elements of this claim. To set forth a claim for false marking under 35 U.S.C. § 292, Novel must demonstrate: (1) marking of an unpatented article, and (2) intent to deceive the public. Given that the Court has granted summary judgment for Braintree on its infringement claims, it is clear that SUPREP is covered by '149 patent. As such, Novel cannot satisfy the first

element of its false marking counterclaim, as it cannot establish the false marking of an unpatented article.

Similarly, even if the Hatch-Waxman Act does not preclude Novel's fourth counterclaim alleging unfair competition under Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), Novel cannot satisfy the requisite elements of this claim. Section 43(a) of the Lanham Act states, in part:

> Any person who, on or in connection with any goods or services, or any container for goods, uses in commerce any word, term, name, symbol, or device, or any combination thereof, or any false designation of origin, false or misleading description of fact, or false or misleading representation of fact, which . . . in commercial advertising or promotion, misrepresents the nature, characteristics, qualities, or geographic origin of his or her or another person's goods, services, or commercial activities, shall be liable in a civil action by any person who believes that he or she is or is likely to be damaged by such act. 15 U.S.C. § 1125(a)(1)(B).

Liability under Section 43(a)(1)(B) of the Lanham Act arises where the claimant makes a commercial message or statement that is either (1) literally false, or (2) literally true but is ambiguous such that it has the tendency to deceive consumers. *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharms. Co.*, 290 F.3d 578, 586 (3d Cir. 2002). Here, since the Court has previously awarded summary judgment to Braintree on its infringement claims, Novel cannot satisfy the above-listed elements of its unfair competition claim under Section 43(a) of the Lanham Act.

Further, the parties seem to agree that with respect to a "claim under section 43(a) of the Lanham Act stemming from a patentee's marketplace activity in support of his patent," Novel "must first establish that the activity was undertaken in bad faith." *Judkins v. HT Window Fashion Corp.*, 529 F.3d 1334, 1338 (Fed. Cir. 2008); *see also Zenith Elecs. Corp. v. Exzec, Inc.*, 182 F.3d 1340, 1353 (Fed. Cir. 1999). Novel noted that "[a] clear case of bad faith can be made

out if the patent holder knows that the patent is not infringed and yet represents to the marketplace that a competitor is infringing. *Id.*; *see also D.P. Wagner Manufacturing , Inc. v. Pro Patch Sys., Inc.*, 434 F. Supp. 2d 445, 461 (S.D. Tex. 2006)" (parenthetical omitted). (ECF No. 181, p. 32-33). Since the Court has previously awarded summary judgment to Braintree on its infringement claims, Novel cannot establish bad faith here.

Finally, even if the Hatch-Waxman Act does not preclude Novel's fifth counterclaim alleging unfair competition under New Jersey law, Novel has failed to establish the required elements of this claim. With the exception of the interstate commerce requirement, "the elements of the unfair competition torts proscribed by New Jersey law and by section 43(a) of the Lanham Act are the same." *SK&F, Co. v. Premo Pharm. Labs., Inc.*, 625 F.2d 1055, 1066 (3d Cir. 1980). As such, the Court's analysis and conclusions with respect to Novel's fourth counterclaim alleging unfair competition under Section 43(a) of the Lanham Act, which are set forth above, apply with full force to Novel's fifth counterclaim alleging unfair competition under New Jersey law.

Accordingly, the Court grants Braintree's motion for summary judgment on Novel's third, fourth, and fifth counterclaims, as these claims appear to be beyond the scope of this Hatch-Waxman Act litigation and lack merit.

Defendant's Rule 56(e) Motion

In a motion pursuant to rule 56(e) motion, Novel asserts that certain of Braintree's responses to Novel's proposed Undisputed Facts under Local Civil Rule 56.1 are "[i]nsufficient," and that the Court should "deem those facts undisputed." (ECF No. 199 at 4, 7).

Local Civil Rule 56.1 provides that a party moving for summary judgment "shall furnish a statement which sets forth material facts as to which there does not exist a genuine issue, in

separately numbered paragraphs citing to the affidavits and other documents submitted in support of the motion." In response, the summary judgment opponent "shall furnish . . . a responsive statement of material facts," in which the opponent "cit[es] to the affidavits and other documents submitted in connection with the motion." L. Civ. R. 56.1. Federal Rule of Civil Procedure 56 governs motions for summary judgment. Rule 56(a) provides that "[a] party may move for summary judgment," and states the circumstances in which summary judgment is appropriate. The remaining sections of Rule 56 provide procedures and parameters for evaluating summary judgment motions. *See* Fed. R. Civ. P. 56(b)-(h). Among these, Rule 56(e) provides for a variety of possible remedies where, on a motion for summary judgment, "a party fails to properly support an assertion of fact or fails to properly address another party's assertion of fact as required by Rule 56(c)."

Novel's 56(e) arguments are without merit. Braintree's response to each of the alleged "undisputed" facts has a legitimate basis. Braintree, as is its right, has legitimately disputed the facts that Novel complains about in its 56(e) motion, even though many are not material to summary judgment. Braintree is not obligated to admit facts it considers to be untrue. In addition, where supposed "uncontested" facts contain vague, ambiguous and imprecise language, a party may refrain from admitting them.

Accordingly, Novel's Rule 56(e) motion is denied.

Defendant's Motion to Strike

Novel filed a motion to strike to (1) preclude Braintree from relying on its argument concerning the term "a patient" and strike portions of the Expert Reply Report of David Peura, M.D., and (2) strike the entirety of the Declaration of David G. Adams in Support of Braintree Laboratories, Inc.'s Motion for Summary Judgment on Novel Laboratories, Inc.'s Third, Fourth,

and Fifth Amended Counterclaims ("the Adams Declaration"), because Braintree failed to disclose its position that the asserted claims of the '149 patent are infringed on a per patient basis. As stated above, and for the following reasons, Novel's motion is denied.

Braintree's "A Patient" Argument

In the District of New Jersey, the "Local Patent Rules" emphasize early disclosure of infringement and invalidity contentions for patent cases arising under the Hatch-Waxman Act. Local Patent Rule 3.6 sets out disclosure requirements for generic drug patent litigation arising under the Hatch-Waxman Act, including infringement contentions for identified Asserted Claims. L. Pat. R. 3.6(g). The rules require leave of court for amendments to contentions, disclosures, or documents required to be filed or exchanged. L. Pat. R. 3.7. In addition, Federal Rule of Civil Procedure 26 provides that in civil litigation in general parties are expected to disclose aspects of their cases during the discovery process. *See e.g.*, Fed. R. Civ. P. 26(e). The Rules provide that a party may be sanctioned for failing to make timely disclosures of required information or to supplement disclosures based on new information. *See* Fed. R. Civ. P. 37(c)(1)(C). Sanction for failing to disclose required information include prohibiting introduction of such withheld information in evidence and striking pleadings in whole or in part. *See* Fed. R. Civ. P. 37(b)(2)(A).

Federal Rule of Civil Procedure 12(f) permits a party to move to strike from any pleading "any insufficient defense or any redundant, immaterial, impertinent, or scandalous matter." Fed. R. Civ. P. 12(f). "A court possesses considerable discretion in disposing of a motion to strike under Rule 12(f)." *Kim v. Baik*, 2007 U.S. Dist. LEXIS 13553 (D.N.J. Feb. 27, 2007) (quoting *River Road Dev. Corp. v. Carlson Corp.*, No. 89-7037, 1990 U.S. Dist. LEXIS 6201, 1990 WL

69085, at *2 (E.D.Pa. May 23, 1990)). Moreover, motions to strike are disfavored and usually will be denied.

Here, contrary to Novel's argument, Braintree sufficiently disclosed its infringement. For example, in its Infringement Contentions, Braintree put Novel on notice that Novel's copy of SUPREP meets the "a patient" limitation of the asserted claims. Braintree's proposed construction of the term "clinically significant electrolyte shifts", which used the term "a subject" instead of the term "any patient" found in Novel's construction, also achieved the same. As Novel was on notice of Braintree's theory, Novel's assertion that Braintree's conduct will prejudice Novel is baseless. In addition, Novel's assertion that the Local Patent Rules require more than Braintree provided is without merit. Nothing in the Local Rules, or the caselaw, requires a patent holder to explain the meaning of every claim term – especially a term, like "a", that has a well-established meaning in patent law – or to identify "a patient" as a term requiring construction.

The Adams Declaration

The Court also declines to grant Novel's motion to strike with respect to the Adams Declaration. The Adams Declaration is admissible because it is factual evidence that is helpful to the trier of fact. *See* Fed. R. Evid. 702; Fed. R. Evid. 704; *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 149 (1999); *Berckeley Inv. Group, Ltd. v. Colkitt*, 455 F.3d 195, 217-19 (3d Cir. 2006). Admissibility of expert testimony is committed to the broad discretion of the trial court. *See Berckeley*, 455 F.3d at 217 ("The District Court has discretion to determine whether expert testimony will help the trier of fact").

Federal Rule of Evidence 702, governing the admissibility of expert evidence, provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:
>
> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue.

(emphasis added). Federal Rule of Evidence 704 provides that "[a]n opinion is not objectionable just because it embraces an ultimate issue." The touchstone of admissibility of expert evidence is thus helpfulness. *See also Berckeley*, 455 F.3d at 217 ("The District Court has discretion to determine whether expert testimony will help the trier of fact").

While testimony as to the governing law of the case, or whether a party complied with its legal duties arising under a particular law, is not admissible, attorneys may provide expert testimony on the custom and practice of a regulated industry and the negotiations of regulated parties with regulators in an area governed by a statutory framework. *See id.* at 217-18. Indeed, courts often permit testimony as to the practice and procedures of a government agency, such as the USPTO. *See, e.g.*, *Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1361 n.2 (Fed. Cir. 2008). Here, the Adams Declaration is helpful to the trier of fact because it provides factual evidence as to the practices and procedures under Hatch-Waxman and FDA Law and their interaction with the patent regime. The Adams Declaration is also helpful because it contains factual evidence of the FDA's conduct towards SUPREP and Novel's ANDA. Finally, nothing in the Federal and Local Rules or case law negates the admissibility of the Adams Declaration. Accordingly, Novel's motion to strike is denied.

Conclusion

For the reasons stated above, Braintree's motion for summary judgment of infringement is granted, and Novel's motion for summary judgment of non-infringement is denied. Braintree's motion for summary judgment on Novel's third, fourth, and fifth counterclaim is also granted. Novel's motion for summary judgment on invalidity, and its motion to strike and Rule 56(e) motion are also denied.

s/Peter G. Sheridan
PETER G. SHERIDAN, U.S.D.J.

January 18, 2013